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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,467	12/22/2000	Paul F. Agris	5051-4741P	2331

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EXAMINER

CHEU, CHANGHWA J 16

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/747,467

Applicant(s)

AGRIS, PAUL F.

Examiner

Jacob Cheu

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3/7. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group II, claims 14-18, and cancelled claims 23-32 without prejudice in Paper No. 9 is acknowledged.
2. The traversal is on the ground(s) that group I, claims 1-13 are product claims used in the method claims of elected group II. This is not found persuasive because group II, directed to a method using antibody to detect incomplete deprotection of a synthetic oligonucleotide which can be practiced by a materially different product, i.e. antibody other than recited in group I. For instance, suppose a thymine dimer is formed, i.e. "protected" by T-T. An antibody specifically recognized this dimer can be used to detect the "incomplete deprotection" process of the oligonucleotide. Therefore group I and group II are deemed to be patentably distinct and independent inventions.
3. As to claims 19-22, a method directed to separating protected from fully deprotected synthetic oligonucleotides. The feature of separating the antibody from the deprotected synthetic oligonucleotides in this group, is not required by the claims of group I and group II.
4. Therefore claims 1-13 and 19-22 are withdrawn from further consideration. The requirement is still deemed proper and is therefore made **FINAL**.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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With respect to claim 14, line 3 "according to claim 1" is vague and indefinite. It is suggested that applicants incorporate features and limitation from claim 1 for clarification.

With respect to claim 15, "A method according to claim 14" is vague and confusing. It is suggested that applicants change "A" to "The" for clarification.

Similarly, claims 16-18 share the same problem as claim 15. Appropriate correction is needed.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 14-16 and 18 are rejected under 35 U.S.C. 102 (b) as being anticipated by Lewis et al.. (USP 5049656)

Lewis et al. teach using antibody specifically recognized impurities, i.e. capping oligonucleotides (covalent bound), for polypeptide or oligonucleotides synthesis process. (Col. 5, line 35-45) Lewis et al. also teach immobilized such antibody on a solid support for immunoassay. (Col. 4, line 56-57) Lewis et al. teach that the chemically capping oligonucleotide, i.e. dinitrobenzoyl group on the oligonucleotide, acts as an antigenic molecule recognized by the antibody. (Col. 14, line 20-30) Lewis et al. teach that binding of the antibody indicates the impure capping still remains on the oligonucleotide, i.e. incomplete deprotection. (Col. 14- Col. 15) Lewis et al. teach that both homogeneous or heterogeneous (i.e. required separation step), immunoassay can be conducted by using the claimed invention. (Col. 4, line 55-64)

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. in view of Tortora et al. (Microbiology 6th edition (1997) Addison Wesley Longman, Inc. page 497)

The reference of Lewis et al. has been discussed but does not explicitly teach using the sandwich assay. Nevertheless, the sandwich assay is a well-known and widely used technique in the art, i.e. such as sandwich ELISA as taught by Tortora et al.. (See page 497) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the method of Lewis et al with the popular sandwich immunoassay as taught by Tortora et al., for the detection of the oligonucleotide because it is well-known and widely used in the art.

Conclusion

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5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 8:30-5:00.

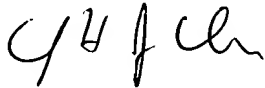
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu

Examiner

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March 24, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

03/24/03